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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/601,997 | 12/15/2000 | James G. Keck | 24743-2307US | 5984 |

20985 7590 10/18/2006

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MINNEAPOLIS, MN 55440-1022

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| EXAMINER |
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EPFS FORD, JANET L

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| ART UNIT | PAPER NUMBER |
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1633

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

14

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/601,997 | | KECK, JAMES G. | |
| | Examiner | | Art Unit | |
| | Janet L. Epps-Ford | | 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-14 and 58-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 and 58-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

3. Due to the ambiguity associated with independent claim 58, Applicant's arguments with respect to newly amended claims 9-14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9-14, and 58-73 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record, and for those reasons set forth below:

Instant claim 58 (and those claims dependent therefrom) remains vague and indefinite to the extent that the instant claim still recites wherein the "antisense strand that, when expressed as RNA, binds to an mRNA transcribed from the target nucleic acid sequence," (see lines 15-16), this statement suggests that the antisense RNA produced from the sense stranded of the cloned double stranded DNA, targets an

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mRNA other than the mRNA product “coded for by a sample nucleic acid in the target nucleic acid” as set forth in the preamble of the claimed method.

Additionally, the nature of the “oligonucleotide family” recited in claim 58, line 7, is vague and indefinite. It is unclear if all of the oligonucleotide family members are designed to target one particular gene target or sample nucleic acid in said target, or if they have random sequences that target multiple genes.

Moreover, the instant claim is incomplete since there is no mention of a control, un-transfected host cell, such that changes in phenotype can be assigned to one particular antisense RNA targeting one particular gene target, by comparison of the transfected host cell, and the un-transfected host cell.

6. Claim 59 (and those claims dependent therefrom, claims 60-63, and 70), lines 2-3 recite “a catalytic domain that cleaves *an* mRNA sequence transcribed from the target nucleic acid,” this phrase is suggestive of multiple mRNA sequences transcribed from the target nucleic acid. However, as stated in claim 58 (from which this claim depends from), the intended objective of the claimed method is to assign a function associated with a product coded for by a “**sample nucleic acid sequence in** a target nucleic acid molecule.” Therefore, it is unclear if the entire scope of claim 59 and those claims dependent therefrom, further limits claim 58, since the method of claim 59 involves wherein the RNA (assuming the RNA here refers to antisense RNA produced from the sense strand in claim 58) cleaves *an* mRNA sequence transcribed from the target nucleic acid.

7. Claim 59, recites the phrase "the RNA," in the first line. However, the metes and bounds of this phrase are vague and indefinite since it is unclear which RNA Applicants are referring to.

8. Due to the ambiguity associated with independent claim 58, and those claims dependent therefrom, the prior art will not be applied until Applicant addresses the above issues.

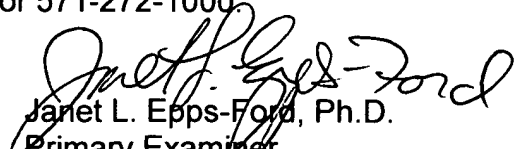
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE